

**REMARKS/ARGUMENTS**

In response to the Final Office action of September 11, 2005, Applicants hereby request re-examination and reconsideration of this application for patent pursuant to 35 USC 132.

**Claim Status/ Support for Amendments**

Claims 1-4 remain pending in the instant application.

**Claim Rejections - 35 USC § 112**

Claims 1-4 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner has indicated that claim 1 is vague. It is pointed out in the instant Office action that the preamble of the claim is not consistent with the body of the claim, and that the Examiner believes the claims ought to recite "a process for producing a displacement assay". The Examiner further indicates that the claims are confusing because the last 2 lines of the claim appear to be detecting a color and relating the presence of color

to the presence of antibody. The Examiner suggests that perhaps the preamble of the claim should be amended to recite a process for performing a displacement assay. Step (c) of the claim was previously thought to be vague in reciting a "conjugated antibody" because it was not clear as to what the antibody was conjugated to.

The above objections/rejections are believed to be addressed via the instant amendments.

Claim 1 has now been amended to clearly recite the steps for "producing" the displacement assay of the invention, and recites:

- a) producing a heat-killed antigen or facsimile antigen;
- b) immobilizing said antigen or facsimile antigen upon a clear and flexible polymer film;
- c) binding a pigmented antibody to said antigen or facsimile antigen; and
- d) washing away any unbound antigen or facsimile antigen;  
[[and]]

wherein a presence of color evidences the presence of said  
[[labeled]] pigmented antibody, and binding of a contaminant  
displaces said pigmented antibody, whereby an absence of color  
signals binding of the contaminant.

The step of "adding a color producing agent which evidences color upon binding with said labeled antibody" has been deleted, since this was inaccurate and led to the prior confusion. The addition of the pigmented antibody in step (c) adds the color producing agent.

Basis for these amendments can be found at pages 13-14 of the originally filed disclosure.

The claim, as instantly amended, more accurately reflects the nature of the invention, which is the production of a displacement assay, upon a clear and flexible film.

The claim is meant to be directed toward the formation of the assay, *per se*, not the actual performance thereof. As such, it is believed that the claim language particularly points out and distinctly claims Applicants' invention.

**CONCLUSION**

In light of the foregoing remarks, amendments to the specification, and amendments to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,

  
Ferris H. Lander  
Registration # 43,377

McHale & Slavin, P.A.  
2855 PGA Boulevard  
Palm Beach Gardens, FL 33410  
(561) 625-6575 (Voice)  
(561) 625-6572 (Fax)

\\\Ns2\server\CLIENT FILES\1900-1999\1965 - Toxin Alert\1965U\_000025 - UT  
PAT\Amendments\1965.025\_FL\_AM2\_v1.wpd